IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: C. R. BARD, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **MDL NO.: 2187**

THIS DOCUMENT RELATES TO:

CAROLYN JONES) **2:11-cv-00114**
_____)

PLAINTIFFS' RESPONSE IN OPPOSITION TO DEFENDANT C.R. BARD, INC.'S MOTION FOR PARTIAL SUMMARY JUDGMENT

COME NOW, Plaintiffs in the above-referenced civil action, and file their Response in Opposition to Defendant C.R. Bard, Inc.'s ("Bard") Motion for Partial Summary Judgment, and shows as follows:

Factual background

Carolyn Jones' implantation and mesh-related injuries[1]

Ms. Carolyn Jones was implanted with an Avaulta Plus anterior and posterior on August 26, 2008 by Dr. David Williams for pelvic organ prolapse.[2] (*See* Deposition of David Williams, MD ("Williams depo."), filed of record by Bard in support of the present motion, at 59:22; 60:8). Dr. Williams, who was trained by Bard to use the mesh repair kit to do the Avaulta procedure, testified that he conducted the surgery as he had been instructed by Bard in a two session training that included cadaver exercises. (*Id.* at 12:19-14:7). Further, Dr. Williams indicated that his Bard sales representative, Justin Winn, was present in the operating room "almost every time

[1] The facts giving rise to a genuine dispute of material fact with respect to Bard's asserted learned intermediary defense, and Bard's failure to warn, are set forth below in the section of Plaintiffs' argument addressing Bard's argument on Plaintiffs' failure to warn claim.

[2] Ms. Jones also had a Bard Align sling implanted at the same time for treatment of stress urinary incontinence.

[he] can remember" and he was complimentary of his surgical techniques and never offered any criticism. (*Id.* at 18:7-19:10). Dr. Williams testified that Ms. Jones recovered well and she was discharged with pain medication, vaginal cream and mineral oil to prevent any bowel strain. (*Id.* at 71:14-21).

At her postoperative check-ups on September 17, 2008 and October 7, 2008, Ms. Jones complained of bladder spasms with urination, continued pain and mild discharge, which Dr. Williams indicated was normal for someone healing from major surgery and that she was healing well from the repair. (Williams depo. at 73:25-75:12). On a subsequent visit on April 6, 2009, Dr. Williams testified that Ms. Jones was doing well, but complained of vaginal spotting and was taking an antibiotic (Cipro) for urinary tract infection. Upon conducting a vaginal examination, Dr. Williams discovered a small area of mesh exposure, and although Ms. Jones was already using Estrace vaginal cream (an estrogen cream) he thought this might resolve with an increased usage of Premarin vaginal cream (also an estrogen cream). (*Id.* at 75:24-77:18). Dr. Williams testified that he didn't see Ms. Jones after that appointment. (*Id.* at 79:21-80:6) After her post-operative visits with Dr. Williams she went back to seeing her nurse practitioner. (Deposition of Carolyn Jones, "Jones depo.", filed in support of Bard's present motion at 87:9-14; 110:9-10).

Ms. Jones was subsequently referred to Dr. Charles Secrest who removed the Avaulta mesh on May 17, 2012 and she said that she learned from Dr. Secrest that "the mesh had splattered and that was part of [her] problem with hurting" and that Dr. Secrest went in very deep to get the mesh out and didn't know if he got it all out or not. (Jones depo., at 34:25). Dr. Secrest's operative report indicates that he performed an extensive mesh removal procedure, and he attempted to remove as much mesh as he could. (Secrest operative report, attached hereto as "**Exhibit 1**").

Ms. Jones continues to suffer serious physical injury and pain and discomfort from the Avaulta product; most notably, Ms. Jones continues to experience leg pain, chronic pelvic pain and lower back pain she attributes to the mesh. (Jones depo., at 34:13-22; 12:6-22).

Argument and Citation of Authority

Legal standard for summary judgment

Summary judgment should be granted only where there is no genuine dispute of material fact. All facts must be construed in a light most favorable to the non-movant, and as the Fourth Circuit has observed, "[t]he non-movant is entitled 'to have the credibility of his evidence as forecast assumed, his version of all that is in dispute accepted, [and] all internal conflicts in it resolved favorably to him.' *Charbonnages de France v. Smith,* 597 F.2d 406, 414 (4th Cir.1979)." Reese v. Alea London Ltd., 332 Fed.Appx. 135, 2009 WL 1426904, *2 (4th Cir.2009).

I. Plaintiffs have pointed to ample evidence to establish their claim for manufacturing defect.

Under Mississippi law, a plaintiff can establish a manufacturing defect by demonstrating that the product deviated in a material way from the manufacturer's specifications or from otherwise identical units manufactured to the same manufacturing specifications. Miss. Code § 11-1-63(a)(i)(1). In addition, "Plaintiffs can establish a manufacturing defect with evidence of inferior or defective materials, or evidence of a malfunction. *See Shelter Ins. Co. v. Mercedes Benz, USA,* No. 1:03-CV-592, 2006 WL 1601770, *1, 2, 2006 U.S. Dist. LEXIS 38011, *3-4 (N.D.Miss. June 8, 2006),*aff'd,* 236 Fed.Appx. 45 (5th Cir.2007) (citing *Cooper Tire & Rubber Co. v. Tuckier,* 826 So.2d 679 (Miss.2002))." Walker v. George Koch Sons, Inc., 610 F.Supp.2d 551, 556 (S.D.Miss. 2009). Plaintiffs have presented evidence to establish a manufacturing defect under each of these alternative methods.

In Cooper Tire & Rubber Co. v. Tuckier, supra, the manufacturing defect alleged by the plaintiff consisted of a separated tire tread which the plaintiff argued was caused by the defendant manufacturer's use of "bad stock" rubber. Cooper Tire, 826 So.2d at 682. The defendant argued that the trial court should have granted its motion for directed verdict because the plaintiffs failed to present any evidence of the manufacturer's specifications for the type of tire at issue, let alone demonstrate any deviation between the specifications and the defective product. Id. The Mississippi Supreme Court held that under the MPLA, a plaintiff could prove her *prima facie* case without putting on evidence of the actual manufacturer's specifications by instead putting on evidence that the defective products were manufactured with inferior or defective materials. Id. at 683. In particular, the plaintiff's theory of the case was that the defect in the tire was caused by use of "bad stock" rubber which had been left out for several weeks over a holiday shut-down at the plant where they were manufactured. Id. The court in Cooper Tire reasoned that use of defective material in the manufacture of an ultimately defective product satisfied MPLA even without evidence of the manufacturer's specifications, since no manufacturer's specifications could reasonably call for substandard materials. Id.

Plaintiff has presented *prima facie* evidence of a manufacturing defect to support her strict liability manufacturing claims, which could also be characterized under Georgia law as an "inadvertent" design defect claim.[3] Plaintiffs' biomaterials and biomedical engineering expert, Dr. Ahmed El-Ghannam, analyzed and tested samples of "pristine" Avaulta Plus and Solo

[3] In Banks v. ICI Americas, Inc., 264 Ga. 732, 734 n. 2 (1994), the Georgia Supreme Court explained the legal standard applicable to an inadvertent design defect versus that applicable to a conscious design choice. While a conscious design choice (which Plaintiffs also claim herein) is analyzed under the risk-utility balancing test, an inadvertent design defect is judged by the same standard as a manufacturing defect because both are subject to measurement against a norm of proper manufacture or design. As set forth herein, there is no contention that the damage to the pristine mesh samples observed and described by Plaintiffs' expert in this case were a conscious design or the expected or intended results of Bard's manufacturing process.

meshes, and he described the damage to the pristine material caused by exposure to thermal and mechanical stresses during the manufacturing process, which he explained affects the mechanical and chemical stability of the device and causes the material to be more susceptible to degradation inside the body. (See, Rule 26 Report of Ahmed El-Ghannam; Supplemental Rule 26 Report of Ahmed El-Ghannam, Ph.D., pp. 5-15).[4] As Dr. El-Ghannam explains in his second supplemental and rebuttal report, the manufacturer of the raw polypropylene material used in the Avaulta products expressly warned that hazardous degradation products (including aldehydes, acids, and low molecular weight hydrocarbons) can be formed and released "**during thermal processing**." (Second Supplemental and Rebuttal Rule 26 Report of Ahmed El-Ghannam, Ph.D, **Exhibit 2**; Material Safety Data Sheet for Marlex HGX-030-01 attached hereto as "**Exhibit 3**", Section 10 "Stability and Reactivity" and Section 11 "Toxicological Information").[5] In its motion to exclude Dr. El-Ghannam's testimony, Bard acknowledges that the defects observed in the pristine mesh and described by Dr. El-Ghannam are, in fact, "manufacturing defects." (Bard El-Ghannam Daubert Brief filed in this case, pp. 15-19).[6]

There is no contention by Bard that it expected or intended for its "pristine" mesh to be

[4] Both Dr. El-Ghannam's initial Rule 26 Report and his Supplemental Rule 26 Report were filed of record herein by Bard in support of its Motion seeking to exclude Dr. El-Ghannam's testimony. Dr. El-Ghannam explains in his Supplemental Report that the heat set process employed by Bard in the manufacture of the Avaulta devices subjects the material to extreme temperatures (290 ± 15° F), as well as mechanical forces during that heating process that significantly exceed the mesh's reported tensile strength (the maximum stress the material can withstand before failure). (El-Ghannam Supp. Report, pp. 6-14).

[5] Moreover, as explained in Dr. El-Ghannam's second supplemental report, the supplier of this polypropylene expressly warned that this material was *not to be permanently implanted in humans*.

[6] When Bard itself has moved to exclude Dr. El-Ghannam's testimony regarding what it concedes in its pleadings are "manufacturing defects," it is unreasonable for Bard to contend that "Plaintiffs have adduced no evidence that the Avaulta Systems implanted in Ms. Cisson had a manufacturing flaw or defect." Bard's Daubert motion seeking to exclude Dr. El-Ghannam is not well-founded for the reasons set forth in Plaintiff's response in opposition thereto.

damaged or altered by the manufacturing process in the manner described by Dr. El-Ghannam, or that the mesh implanted in Ms. Cisson was intended or expected to degrade inside her body. To the contrary, Bard represented that its material was "inert," biocompatible and permanent. The degradation (cracks, fissures, melting) demonstrated by Plaintiffs here is analogous to the manufacturing cracks and defects observed and described by the plaintiff's expert in Reed v. Smith & Nephew, Inc., 527 F.Supp.2d 1336, 1354 (W.D.Okla.2007), which led the court to deny the defendant manufacturer's summary judgment motion on manufacturing defect. In the recent case of Davis v. C.R. Bard, Inc., 2012 WL 6082933, *7-8 (E.D.Mich. 2012), the court denied Bard's summary judgment motion on the plaintiff's manufacturing defect claim under closely analogous facts. Davis involved another defective implantable device (a vena cava filter) sold by Bard, which the plaintiff argued contained a manufacturing defect (poor surface finish) that rendered the filter prone to fracture. Although Bard said the plaintiff could not prove that his filter fracture was caused by any defect, the court in Davis held that the plaintiff's evidence – particularly that the filters had surface flaws that Bard did not intend – was sufficient to survive summary judgment on the manufacturing defect claim.[7] Likewise, the damage to the Avaulta mesh caused by the manufacturing process described by Plaintiffs' experts precludes summary judgment on Plaintiffs' manufacturing defect claim here.

While more than sufficient to establish a genuine dispute of material fact, Dr. El-Ghannam's testimony is not the only evidence of a manufacturing defect. Bard represented that the pore size for its Avaulta Solo mesh was 1.3 mm in the central portion and 1.0 mm in the

[7] "In examining the fractured filters, [the plaintiff's expert] stated that the poor surface finish of the filter's limbs likely a manufacturing defect on those components that could have been removed by post-manufacture electropolishing, or improvement in manufacturing procedures and quality control…. Plaintiff notes that '**unless Bard's position is that the [filter] is designed to have serious surface flaws that rendered it prone to fracture, the device as manufactured was not in its intended condition**....'" Davis, supra at *8 (Emphasis added).

arms. (AVA2E0010906, **Exhibit 4**); See also, AVA2E0007362, **Exhibit 5** (same representations to doctors in Physician Education materials)). However, Plaintiffs' biomaterials expert Anthony Brennan, Ph.D. measured the pores of the Avaulta Solo mesh and found – *on average* – only .52 x .74 mm in the arms; and just 1.08 x .59 mm in the center portion. (See, Rule 26 Report of Anthony Brennan, Ph.D., a copy of which was filed by Bard in support of its motion to exclude Dr. Brennan, p. 27). In fact, Bard's own internal measurements of its pores demonstrate that the pore sizes were far below those in its representations to doctors and to its sales force. (AVA20096615, **Exhibit 6** (showing measurements of the three largest pores in the design pores, with two of those pores showing lengths and widths significantly smaller than what Bard represented, and actually not even measuring all pores because they "were not significant enough in size to measure.")).

Finally, the evidence establishes that Bard knowingly selected an improper material to manufacture the Avaulta devices. As more fully set forth in Plaintiff's response in opposition to Bard's separate punitive damages summary judgment motion filed in this action, the manufacturer of the polypropylene resin used to manufacture these products expressly prohibited the use of this material for human implantation. Bard not only ignored the supplier's unambiguous warning, but actually concocted and employed a scheme to obtain the resin so that it could utilize the mesh for human implantation without the supplier (or others within Bard's processing chain) discovering that it was doing so. As noted above, "Plaintiffs can [also] establish a manufacturing defect with evidence of inferior or defective materials," Walker v. George Koch Sons, Inc., 610 F.Supp.2d 551, 556 (S.D.Miss. 2009), such as the "not for human use" polypropylene at issue here. See also, Cooper Tire & Rubber Co. v. Tuckier, 826 So.2d 679, 682 (Miss.2002) (irrespective of manufacturer's specifications, use of an improper material –

"bad stock" rubber there – gives rise to a manufacturing defect claim). Plaintiff's evidence is more than sufficient to survive Bard's summary judgment motion on her manufacturing defect claim, and Bard's motion should be denied.

II. Bard's contention that Plaintiffs' failure to warn claim is barred as a matter of law based on its "warnings" contained within its IFU, and its learned intermediary defense, cannot withstand scrutiny.[8]

Under Miss Code § 11-1-63(c)(ii):

> An adequate product warning or instruction is one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates sufficient information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to an ordinary consumer who purchases the product; or in the case of a prescription drug, medical device or other product that is intended to be used only under the supervision of a physician or other licensed professional person, taking into account the characteristics of, and the ordinary knowledge common to, a physician or other licensed professional who prescribes the drug, device or other product.

In short, "[a]n adequate warning is one reasonable under the circumstances." Bennett v. Madakasira, 821 So.2d 794, 805 (Miss. 2002), *abrogated on other grounds*, Hutzel v. City of Jackson, 33 So.3d 1116, 1122 (Miss. 2010). "To be reasonable, the warning should neither understate nor overstate the known risks associated with the use of a particular product." Janssen Pharmaceutica, Inc. v. Bailey, 878 So.2d 31, 58 (Miss. 2004) (holding that adequacy of prescription drug warning was for the jury, even though the plaintiffs' expert "knew of nothing else [manufacturer] could have done to make their labeling more adequate, except to make them less frequent," and the doctors who prescribed the drug for the 10 trial plaintiffs almost uniformly testified that they considered the warnings adequate; plaintiffs' verdict reversed and

[8] Plaintiffs note that Bard's Brief includes a footnote advising that a California State court jury in the Scott v. Bard Avaulta product liability case rendered a defense verdict for Bard on the plaintiffs' failure to warn claim in that case. Bard's reliance on the Scott jury verdict as support for its summary judgment motion is curious because it shows that the failure to warn claim was, in fact, submitted to the jury there. That fact in itself demonstrates that summary judgment is inappropriate. Bard's discussion of the Scott case also conspicuously fails to mention that the jury there rendered a multi-million dollar verdict against Bard.

remanded on other grounds).[9] The issue of the adequacy of the warning "is usually resolved by the trier of fact." Bennett, supra at 805; Janssen, supra at 57 (the "issue of a warning's adequacy is factual and usually will be resolved by the trier of fact."). Furthermore, "[a] duty that is subsumed within the duty to warn is the duty of a manufacturer 'to test and inspect its product' in a way that is 'commensurate with the dangers involved.'" Wagoner v. Exxon Mobil Corp., 813 F.Supp.2d 771, 793-94 (E.D.La.2011); See also, In re: Avandia Marketing, Sales Practices and Prods. Liab. Litig., 817 F.Supp.2d 535, 547 (E.D.Pa.2011) ("A manufacturer is not excused if it remains purposefully ignorant of a particular risk. The duty to warn is thus a continuing one, and obligates a manufacturer to conduct research and otherwise investigate risks associated with its products, and then update warnings as appropriate.").

In Bennett, supra, the plaintiff alleged that the defendants' package insert for the prescription medications at issue did not adequately convey the risks of the drugs' propensity the potential to cause violent behavior. 821 So.2d at 805. Even though the prescribing doctor testified that he considered the warnings adequate, and had no criticism of the warnings, the Mississippi Supreme Court ruled that such testimony was insufficient "as a matter of law" to resolve the question of the adequacy of the warning. Id. at 806 (citing Hurley v. Lederle Labs. Div. of Am. Cyanamid Co., 863 F.2d 1173, 1178 (5th Cir.1988)). In fact, in Bennett, the court found that there was a question of fact as to both the adequacy of the warning and causation, in spite of the prescribing doctor's testimony there that *he still would have prescribed the medication* even if the warning urged by the plaintiff would have been in the package insert. Id.

[9]In McNeil v. Wyeth, 462 F.3d 364, 370 (5th Cir.2006), the Fifth Circuit reversed the district court's grant of summary judgment to a pharmaceutical manufacturer on the plaintiff's failure to warn claim. Although the manufacturer warned of a "higher" risk with long-term use of its product, the Fifth Circuit held that "the mere statement that the risk increases with use does not put a physician on notice that the increase in risk is of a completely different order of magnitude and class of risk. Thus, a jury could find that the risk of developing [the plaintiff's complication] from long-term use was not just higher, but that it was 'significantly' higher, and that the label was therefore misleading and inadequate."

at 806. The court concluded that the prescribing doctor's testimony as to what he would have done in light of a different warning "is subject to a credibility determination." Id. at 807-08. No such "credibility determination" need be made in this case. Here, as discussed more fully below, Ms. Jones' implanting physician testified unequivocally that there was a wealth of information about the risks with the Avaulta Plus product known to Bard that were not made known to him, and if he had been made aware of those risks, he would not have used the product. Bard's "warnings" set forth in its IFU are inadequate on their face, and particularly as applied to the specific facts in Ms. Jones's case.

The facts regarding Bard's warnings and learned intermediary defense are analogous to the facts at issue in Barrow v. Bristol-Myers Squibb Co., 1998 WL 812318 (M.D.Fla.1998), which involved an allegedly defective silicone breast implant. The plaintiff in Barrow suffered, *inter alia*, "capsular contracture" (where the implant was deformed by foreign body reaction and encapsulation). Even though the defendant's package insert and the doctor's consent form both contained a warning regarding capsular contracture, and although her implanting surgeon discussed that potential complication with her, the court held that the learned intermediary doctrine did not bar the plaintiff's claims. The court observed that neither the consent form nor the package insert "made clear the extent and probability of such capsule contracture," and "[n]o evidence was presented that [the doctor] independently knew of the extent and probability of capsule contracture." Id. at *32; See also, Id. at *34-*36 (discussing same failures to warn under negligence theory). The court further discussed several additional risks of the product that the defendant failed to warn about, including "upon explantation, silicone gel may remain in the body," "the loss of breast tissue in the event of explantation," "the possibility and extent of

distortion of the breast from capsular contracture," and the extent of the scarring and sensitivity that could result from explantation. Id. at *32 and *34-*36.[10]

The court in Barrow also addressed the plaintiff's fraud and negligent misrepresentation claim, which were grounded in part on the defendant's failure to disclose that in spite of its representation that "[s]ilicone materials used in the production of these products…are among the most nonreactive implant materials known for this application," it had never actually tested for the effects of silicone gel in the body. Id. at *43. The court also held that the defendant improperly failed to disclose certain adverse results in some of the laboratory animals during preclinical testing. Id. at *43. Furthermore, the court addressed the same failure to disclose information about the risks known to the company (extent of capsular contracture, breast deformation, consequences of removal surgery, etc.) addressed in the context of the plaintiff's failure to warn claims. Id. at *44-*46. The court held that in light of the defendant's knowledge, these failures amounted to material misrepresentations sufficient to support a claim for fraud and negligent misrepresentation.

While Bard included a list of potential complications in its IFU, Bard unquestionably failed to warn of numerous known risks associated with its products. Initially, Bard never warned any doctor or patient that it was utilizing a material that was *expressly prohibited* by its supplier from being used for permanent implantation in humans. That fact, *in and of itself*, precludes summary judgment for Bard on the adequacy of its warning (as well as on punitive damages). Zeigler v. Clowhite Co., 234 Ga.App. 627, 629 (1999) (failure to include warning on

[10] See also, Horrillo v. Cook, Inc., 2012 WL 6553611, *4-*5 (11th Cir.2012) (even though doctor admitted knowledge of slight risk of stroke, where facts were disputed as to whether implanting doctor's knowledge was substantially the same as defendant's about stroke risk associated with stent, summary judgment on learned intermediary improper); Toole v. McClintock, 999 F.2d 1430, 1433 (11th Cir.1993) (although breast implant patient's doctor knew of risk of complication suffered by the plaintiff, he did not understand the significance of the risk, and had he known he would have warned his patient accordingly; defendant's directed verdict and JNOV on learned intermediary/failure to warn properly denied).

product label that was included in separate MSDS for chemical component precluded summary judgment on failure to warn and punitive damages claim).

In spite of its knowledge, Bard never provided any warning that polypropylene presented a *higher risk* of erosion, infection (due to enhanced foreign body reaction), and scar tissue formation (instead of vascular ingrowth) or that "[i]n some cases of erosion, mesh has been observed to unravel, creating a sharp 'fishing line' effect, which can slice through the patient's tissues." (AVA2E1095328, **Exhibit 7**). Bard likewise never warned doctors or patients that it knew polypropylene "cannot provide functionality" of native tissue, and is "not effective in young/active patients." (AVA2E8019305, **Exhibit 8**).

Bard never warned any doctor or patient that it had never conducted any testing of its mesh arm design prior to implanting the product in women, but instead said, "I think we say with porcine side wall attachment is key and with Avaulta the arms replace this necessity. Prove us wrong!" (AVA2E0100304, **Exhibit 9**).

Bard had knowledge that the rectangular-shaped mesh arms of the Avaulta Plus and Solo products could tear tissue as they are pulled through the much smaller, round trocar tunnel. (See, screen-shot photographs from Bard Avaulta procedural training video (AVA20168449) attached hereto as **Exhibit 10** (showing intact mesh and arms prior to insertion), **Exhibit 11** (showing deformed mesh arm being pulled by trocar on left side of photo), and **Exhibit 12** (showing deformed mesh arm being pulled through trocar tunnel on right side of photo)). In July 2006, before the Avaulta Plus and Solo products were even cleared for sale, a Bard sales manager warned that physicians "see tearing the arm through the tissue…as a major disadvantage." (AVA2E0218345, **Exhibit 13**). During its own lab testing on cadavers for the Avaulta Plus, Bard's physicians noted there was "tissue tearing during pulling [of the] arms."

(AVA2E0393763 – AVA2E0393764, **Exhibit 14**). Several physicians also advised Bard, through its sales personnel, of the issues associated with the mesh arms, indicating that the "sawing of the tissues" was a cause for concern.[11] In spite of its knowledge of this serious problem, Bard never warned any doctor or any patient that the mesh arms could cause any damage to the patient.

No warning was ever provided by Bard that would tell doctors or patients that the central portion of the Avaulta Plus mesh (referred to as "hybrid") was measured by Bard to be *more than five times more stiff* than that of the Avaulta Solo. (AVA20023354, **Exhibit 15**). Likewise, Bard never warned Plaintiff's doctors that "[w]ith the Avaulta Plus there is a **higher risk** of delayed healing/extrusion/rejection etc **because of the porcine**." (AVA2E0799229, **Exhibit 16** (Emphasis added); See also, AVA2E0094647-94648, **Exhibit 17**) (Bard "For Internal Use Only" memo explaining that porcine collagen patch sewn to the Avaulta Plus was known to "cause[] a **greater inflammatory response** than does pure polypropylene," and explaining that "[i]ts **increased mass, thickness, and stiffness as a result of the collagen may also contribute to the patient's reaction to the implant**," and acknowledging that the collagen component of the Avaulta Plus causes an adverse reaction associated with granulation tissue, foul-smelling discharge, and spotting "[**b**]**y increasing the inflammatory response**….") (Emphasis added)).[12]

[11] See e.g. August 21, 2006 summary of feedback from Bard's sales personnel where another Bard sales manager reports concerns from physician customers regarding tearing of the tissue. (AVA2E0119677**, Exhibit 18)**; September 2, 2007 email from physician to a Bard sales manager stating that the Avaulta Solo mesh "is going to cut through tissues like a saw." (AVA2E0116773, **Exhibit 19**), October 10, 2007 email from Bard's Director of Marketing stating that the doctor who sent the September 2, 2007 email is "not alone in his concerns [about the arm sawing effect]." (AVA2E1439452, **Exhibit 20**).

[12] No other surgical material sold by any other company combined a sheet of porcine collagen sewn onto a polypropylene mesh like the Avaulta Plus. The fact that this unique collagen patch was known to create a "higher risk" of complications, and to cause a "greater inflammatory response" than "pure polypropylene," makes its IFU statement that the adverse reactions "are those typically associated with surgically implanted materials" inadequate on its face.

Much like the "capsular contracture" issue in Barrow, Bard failed to warn of the probability, severity and serious adverse health effects it knew to be associated with mesh shrinkage.[13] While Bard's IFU generically lists "scarification and contraction," it failed to warn that the inadequate pore size of the Avaulta mesh and the density of its mesh arms were known to cause increased foreign body encapsulation, and that this scar plate formation was known to cause mesh shrinkage of up to 30%-50%. (AVA2E0074398-74399, **Exhibit 21**). Bard never warned any doctor that the pore size was less than half of what Bard recognized to be the minimum necessary, and the weight of the mesh arms were more than twice the maximum identified by Bard in order to avoid excess shrinkage. (Id.).[14] Bard also never warned that the mesh arms would shrink asymmetrically, or that scar plate can entrap nerves.

Furthermore, Bard's minimizing disclaimer that "[p]otential adverse reactions are those typically associated with surgically implantable materials" renders the entire statement inadequate in light of the known association between the specific material and design characteristics of the Avaulta products and the increased risks to patients. As Bard itself acknowledged, "*[m]aterial selection is directly responsible for the performance and associated clinical outcomes,*" and stated that "*[m]aterial selection to date has accomplished the structural repair but is associated with various morbidities including dyspareunia, pain, erosion, extrusion,*

[13] In McNeil v. Wyeth, 462 F.3d 364, 370 (5th Cir.2006), the Fifth Circuit reversed the district court's grant of summary judgment to a pharmaceutical manufacturer on the plaintiff's failure to warn claim. Although the manufacturer warned of a "higher" risk with long-term use of its product, the Fifth Circuit held that "the mere statement that the risk increases with use does not put a physician on notice that the increase in risk is of a completely different order of magnitude and class of risk. Thus, a jury could find that the risk of developing [the plaintiff's complication] from long-term use was not just higher, but that it was 'significantly' higher, and that the label was therefore misleading and inadequate."

[14] This is but one of a series of documents wherein Bard's Research & Development department openly acknowledge the shortcoming of the design of the Avaulta Plus and Solo device, as more fully discussed in Plaintiffs' Separate Statement of Facts in response to Bard's separate summary judgment motion addressed to punitive damages.

dehiscence, and abscess to name a few." (AVA2E0759629, **Exhibit 22**). In other words, Bard knew that these morbidities are not "those typically associated with surgically implantable materials," but instead were the direct result of Bard's material selection so its statement to that effect was at best an attempt to downplay the increased risks known to be associated with these products. In the recent Davis decision discussed above, which involved another defective implantable device (a vena cava filter) sold by Bard, the court denied Bard's motion for summary judgment on the plaintiff's failure to warn claim involving a filter fracture. 2012 WL 6082933 at *9-10. Even though the plaintiff's implanting physician testified that he made an informed decision to use Bard's device in spite of his knowledge of the risk the product could fracture, the court in Davis observed as follows:

> While the warning in the…filter's information packet did disclose fracture as a risk, **it did not provide any estimation of the magnitude of said risk and, in fact, downplayed the risk by saying that "[m]ost cases of fracture" did not result in significant harm to the patient**. Id. (Emphasis added).

Accord, Maynard v. Abbott Laboratories, 2013 WL 695817, *5 (E.D.Wis.) ("Implicit in the duty to warn is the duty to warn with a degree of intensity that would cause a reasonable man to exercise for his own safety the caution commensurate with the potential danger.").

Bard also never warned any doctor that these products had never been tested for use in the female pelvic floor, had never been determined to be safe and effective for use in the pelvic floor, or that they were actually designed for general surgical use in other areas of the body. Bard never warned anyone that the materials used were known to be too strong and to have inadequate pore size for use in the pelvis, in spite of its knowledge. As Bard itself has admitted, these products were not appropriate for use in the pelvic floor: "*It is our belief that until fairly recently (~2008) the available surgical mesh products used for POP repair may have been overengineered with regard to excess strength and minimal pore size when used in the pelvic*

floor. ***This shouldn't be surprising*** *since the mesh products originally adopted for pelvic floor repair were designed (and cleared) for more general surgical uses*…." (AVA2E0864857, **Exhibit 23**) (Emphasis added).

Much like the defendant's representation in Barrow that silicone was "among the most nonreactive implant materials," Bard represented that material used in the Avaulta products was "inert." (See, e.g., AVA20036791, **Exhibit 24** (Avaulta physician training materials stating that "Synthetic mesh is ideal material for [pelvic floor repair]" because it is "strong, [and] inert.")) (Emphasis added). Like in Barrow, however, Bard never disclosed the fact that it had never conducted any testing to determine the potential for degradation of polypropylene in the body or the effects thereof, nor did Bard warn that the Avaulta Plus and Solo meshes are susceptible to degradation inside the body. In spite of **explicit cautionary provisions in the MSDS** for the raw material used to manufacture these products (which, again, was *expressly prohibited for human implantation*), Bard never warned any doctor or any patient that the material may react to oxidizing agents (which are known to exist in the body),[15] or that thermal processing (such as Bard's heat set process) can form hazardous decomposition products that can have deleterious health effects. (Marlex HGX-030-01 MSDS (**Exhibit 3** above) Section 10 "Stability and Reactivity" and Section 11 "Toxicological Information"). See, e.g., Zeigler v. Clowhite Co.,

[15] Oxidizing agents such as peroxide are known to be created in the body by macrophages and leukocytes as they attempt to eliminate a foreign body (like mesh). See, e.g., Ali, S.A.M., et al., *The Mechanisms of Oxidative Degradation of Biomedical Polymers by Free Radicals*, **Journal of Applied Polymer Science**, Vol. 51, 1389-98 (1994) at 1392 (explaining that super-oxide and hydrogen peroxide are "reactive oxygen species" formed by cells during "phagocytosis," the process in which the cells attempt to ingest foreign matter) (a copy of this article is attached to Plaintiffs' separate response to Bard's punitive damages summary judgment motion).

supra at 629 (where warning contained in MSDS was not included on product label, summary judgment on failure to warn claim improper).[16]

Like in Barrow, Bard never warned or disclosed to any doctor that animal testing performed by Bard on the Avaulta products had demonstrated many of the same serious complications later experienced by the women implanted with these devices, and Bard never disclosed that its testing failed to demonstrate that these products were safe to use in humans.[17] Bard likewise never warned any doctor that it had refused to conduct any clinical study on the products – either before or after the products were sold – in spite of its own medical advisor's request that pre-market and post-market clinical studies needed to be performed (James Ross depo. (**Exhibit 25**), p. 119:9 – 120:3; 145:8 – 147:3; 246:10 – 247:9).

Also, like in Barrow, Bard never warned any doctor that if mesh removal were necessary (as it has been in every one of these bellwether Plaintiffs), such would require major invasive surgery that very few doctors are qualified to perform – and that even with surgery, it may be impossible to remove all of the mesh and that patients could be left with chronic, intractable pain and scarring.[18] In fact, Bard provided no warning whatsoever about the potential for removal, or

[16] As set forth in Plaintiffs' response in opposition to Bard's summary judgment motion on Plaintiffs' punitive damages claim, the published scientific literature has demonstrated for years the oxidative degradation of polypropylene, and the effects of thermomechanical stresses on polypropylene that render the material susceptible to degradation inside the body.

[17] Like the adverse animal test results in Barrow, Bard's studies revealed the following complications: chronic inflammation, encapsulation, enhanced foreign body response, hematomas, seromas, and abscesses. (AVA2E0314818, **Exhibit 26**; AVA2E0160012 **Exhibit 27**). Jennifer Mercuri, Bard's employee responsible for conducting animal testing on these products, acknowledged that the purpose of the animal testing was to determine if the products could be safely used in women. (Mercuri depo. (**Exhibit 28**), p. 214:14 – 215:14). However, she admitted that she did not draw the conclusion from any of her testing that the product could be safely used in women, and that she was not suggesting to women or to doctors that these studies showed that these products could be safely implanted in women. (Id., p. 213:12-17; 214:14 – 215:14).

[18] This failure to warn is especially troubling when it is considered that Bard rejected a recommendation from its own Medical Director, Dr. David Ciavarella, for a "true phase I study" for the Avaulta products

the potential necessity of surgical intervention in the event of complications. As observed in Barrow, these myriad failures are not only sufficient evidence of the inadequacy of Bard's warnings to survive summary judgment under a strict liability and negligence standard, they are actually evidence of fraud and misrepresentation.

The learned intermediary doctrine would affect a plaintiff's failure to warn claim *only* "[w]here a learned intermediary has actual knowledge of the substance of the alleged warning and **would have taken the same course of action even with the information the plaintiff contends should have been provided.**" Wheat v. Sofamor, 46 F. Supp.2d 1351, 1363 (N.D. Ga. 1999) (Emphasis added). That is demonstrably not the case here; Ms. Jones's implanting doctor Dr. Williams testified that he would not have implanted the Avaulta product in Ms. Jones had he been made aware of everything that Bard knew about the dangers and increased risks associated with this product. See also, Guenther v. Novartis Pharm. Corp., 2013 WL 1498162, *2 (M.D.Fla. 2013) (applying learned intermediary rule under Ga. law, and holding that plaintiff's testimony that he would not have taken medication had he been made aware of risk known to manufacturer was sufficient to defeat summary judgment, even though his prescribing doctors continued to prescribe drug to others despite knowledge of same risk).

Bard never warned Dr. Williams about any of the following: persistent delayed healing; intense scar plate formation; scar plate formation with adjacent permanent nerve injury; excessive mesh contraction or shrinkage resulting in surrounding nerve damage; the possibility for mesh degradation or fragmentation; mesh creeping or elongating or losing its shape; elasticity problems; chronic or recurring infections; or permanent vaginal or rectal nerve damage.

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specifically because he was afraid the products "will be hard to insert **and even harder to remove**." (AVA2E8054277, **Exhibit 29**) (Emphasis added). Similarly, before these products were sold, Bard recognized that one of the weaknesses in pelvic floor repair kits was "trepidation surrounding removal of kit system should something go wrong long-term." (AVA20002063, **Exhibit 30**).

(Williams depo., 37:3 – 39:4). No one from Bard ever informed Dr. Williams that the polypropylene mesh used in the Avaulta products could shrink up to 30 to 40%, and if he had known that, it would probably have kept him from using the product. (Williams depo., 28:18-29:5).

Dr. Williams was asked about information known to Bard that he was not provided, and whether that information would have made a difference to him in his decision to use the product. For example, he testified that if he had known that Bard had not conducted adequate testing to establish the safety and effectiveness of its pore size, that was absolutely information that he would have liked to have known about, and he would not have used the product if he knew that had not been done. (Williams depo., pp. 21:4-22:7). Similarly, Dr. Williams testified that he probably would not have used the product if he had known that Bard had done no premarket testing regarding the degradation of polypropylene. (Id., 22:8-16). Dr. Williams testified that if he had known that the manufacturing process, through heat and stress, weakened the product, he would not have used it. (Id., 22:17-25). He testified that if he had known that Bard had done no testing to mate the properties of mesh to the natural movement and properties of the pelvis, he probably would not have used the product. (Id., 23:1-13). If he had known that Bard did not conduct adequate testing to determine whether the mesh would deform or curl under stress, that would have changed his opinion as to using the product. (Id., 23:14-25). Dr. Williams testified that he would have liked to have known that Bard failed to test the extent to which the mesh would deform after it was implanted. (24:1-8).

Dr. Williams explained that he would have liked to have known that Bard had done no testing to determine whether the porcine component of the Avaulta Plus actually creates a greater inflammatory response, and in fact, he said that when he later learned that this was the case, he

stopped using the product. (Williams depo., 24:19-25:2). Dr. Williams also explained that he would have liked to have been made aware that Bard had never done testing regarding whether the addition of the porcine dermis caused delayed healing or infection, and that would have changed his mind about using the product – he would not have used it. (Id., 26:3-22). He later testified that no one from Bard ever told him that Bard had actually learned that the collagen created a higher inflammatory response, and if he had known that, he would never have used the product. (Id., 39:23-40:5). Moreover, Dr. Williams testified that although he was told that Bard had added the collagen in order to decrease inflammation and promote tissue growth, Bard "kind of got showed the opposite." (Id., 25:10-24; See also, 39:14-18).

Dr. Williams was never told and he would have liked to have known that a key opinion leader had recommended that Bard conduct premarket randomized controlled trial on the Avaulta products, and volunteered to do the trial, but that Bard had refused. (Williams depo., 26:23-27:8). He testified similarly that he would have liked to have known that a key opinion leader had recommended and offered to do a post-market study on the Avaulta that Bard also refused, and he said that too would have changed his mind about using the product. (Id., 27:9-21).

Bard also never warned or instructed Dr. Williams regarding the difficulty in removing the product in the event removal was necessitated, or how to try and get the product out of the body. (29:21-30:6).

Given the inadequacy of Bard's warnings for the Avaulta product, coupled with Dr. Williams' testimony that he would not have implanted the Avaulta product in Ms. Jones had he been made aware of the numerous risks of the product known to Bard, Bard's summary judgment motion on Plaintiffs' failure to warn claim is unfounded and should be denied.

This 22nd day of April, 2013.

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CERTIFICATE OF SERVICE

I hereby certify that on April 22, 2013, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this M.D.L.

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